Complete Summary

GUIDELINE TITLE

Management of diabetes. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of diabetes. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2001 Nov. 50 p. (SIGN publication; no. 55). [388 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Gestational diabetes
- Complications of diabetes mellitus, including diabetic cardiovascular disease, diabetic nephropathy, diabetic retinopathy and visual impairment, and diabetic foot disease

GUIDELINE CATEGORY

Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nephrology
Nursing
Obstetrics and Gynecology
Ophthalmology
Pediatrics
Podiatry
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Pharmacists
Physician Assistants
Physicians
Podiatrists
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

- To provide an updated evidence-based approach to influence current diabetic practice in order to reduce the burden of long-term complications, both microvascular and macrovascular, as well as improve pregnancy outcome for the mother with diabetes
- To incorporate the new World Health Organization diagnostic criteria for diabetes mellitus which were implemented in the United Kingdom in June 2000

TARGET POPULATION

- Children and adults with diabetes mellitus, type 1 or type 2
- Pregnant women with gestational diabetes

INTERVENTIONS AND PRACTICES CONSIDERED

Management of children and young people with diabetes

1. Screening for type 1 diabetes (not recommended)
2. Home-based management programme
3. Insulin therapy
4. Diet therapy
5. Psychological interventions
6. Screening for diabetic complications and associated conditions

Lifestyle management

1. Delivery of lifestyle interventions based on valid theoretical framework
2. Multidisciplinary lifestyle intervention programmes
3. Self-monitoring of glycemic control (considered but no specific recommendations made)
4. Screening for and treatment of depression
5. Avoidance of hypoglycemia
6. Smoking cessation therapy, as needed (nicotine replacement therapy, bupropion, clonidine, nortriptyline)
7. Exercise and physical therapy, including advice on avoiding hypoglycemia during exercise
8. Dietary interventions and weight control
9. Use of alcohol

Management of diabetic cardiovascular disease

1. Lifestyle modification as primary prevention
2. Glucose lowering therapy (metformin, chlorpropamide, glibenclamide, and insulin)
3. Antihypertensive therapy
4. Aspirin therapy
5. Lipid-lowering therapy
6. Thrombolytic therapy after myocardial infarction
7. Coronary revascularization procedures
8. Beta-blocker therapy
9. Antiplatelet therapy (e.g., clopidogrel and aspirin)
10. Angiotensin-converting enzyme (ACE) inhibitor therapy

Management of diabetic nephropathy

1. Screening procedures (urinary albumin, serum creatinine measurements)
2. Maintenance of good glycemic control and tight blood pressure control
3. Angiotensin II antagonist therapy
4. Reduction in dietary protein

Prevention of visual impairment

1. Risk factor modification
2. Screening for retinal disease (retinal photography, slit lamp biomicroscopy, dilated direct ophthalmoscopy)
3. Laser photocoagulation treatment for sight-threatening conditions
4. Vitrectomy
5. Cataract extraction in diabetes
6. Rehabilitation in diabetic eye disease

Management of diabetic foot disease

1. Patient education in foot care
2. Foot screening
3. Structured diabetic foot care
4. Pharmacologic therapy for foot infections (granulocyte-colony stimulating factor, growth factors)
5. Arterial reconstruction

6. Tissue replacement
7. Treatment of diabetic nephropathy
8. Diagnosis and treatment of Charcot's foot

Management of diabetes in pregnancy

1. Contraception and pre-pregnancy care
2. Nutritional management
3. Optimisation of glycemic control
4. Management of pregnancy complications
5. Fetal monitoring and delivery
6. Breast feeding and postnatal care
7. Management of gestational diabetes

MAJOR OUTCOMES CONSIDERED

- Prevalence of diabetes and diabetes-related complications
- Efficacy of secondary prevention strategies, management strategies, and treatments on factors, such as glycemic control, quality of life, health outcomes and rates of diabetic related complications (i.e., psychological, metabolic, microvascular, cardiovascular, and pregnancy outcomes)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

All searches covered systematic reviews, meta-analyses, and randomized controlled trials. Where appropriate, searches were extended to cover observational studies. Due to the wide subject coverage of these guidelines, a large number of topic-specific searches were required. All searches covered the Cochrane Library, Embase, Healthstar, and Medline. In appropriate cases searches were extended to cover CINAHL and PsychINFO. All searches covered the period 1991-2000. Searches for the section on children and young people were extended back to 1980. Internet searches were carried out on the Web sites of the Canadian Practice Guidelines Infobase, the New Zealand Guidelines Programme, and United States National Guidelines Clearinghouse. Searches were also carried out on the search engines Northern Light and OMNI, and all suitable links followed up. The Medline version of the main search strategies and notes on the coverage of ancillary searches can be found on the Scottish Intercollegiate Guidelines Network (SIGN) Web site, in the section covering supplementary guideline material. The main searches were supplemented by material identified by individual members of the development group.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomized controlled trials, or randomized controlled trials with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or randomized controlled trials with a low risk of bias

Meta-analyses, systematic reviews, or randomized controlled trials with a high risk of bias

2++: High quality systematic reviews of case control or cohort or studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g. case reports, case series

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. Scottish

Intercollegiate Guidelines Network has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developer's Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN website.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the group are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of

recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Grade A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or randomized controlled trial rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rate as 2++

Grade D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held at the Royal College of Physicians of Edinburgh on 11 December 2000. The draft guideline was also available on the Scottish Intercollegiate Guidelines Network Web site for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The guideline was reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. The Scottish Intercollegiate Guidelines Network is very grateful to all of these experts for their contribution to this guideline. The specialist reviewers and Editorial Group for this guideline are listed in the "Supporting Documentation" available on the Scottish Intercollegiate Guidelines Network Web site.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

The strength of recommendation grading (A-D) and level of evidence (I++-4) are defined at the end of the "Major Recommendations" field.

Children and Young People with Diabetes

Diagnosis and Epidemiology

Type 1 Diabetes

B: Screening for pre-type 1 diabetes is not recommended in either the general population or in high risk children and young people.

Cystic Fibrosis and Diabetes

C: Patients with cystic fibrosis should be screened annually for diabetes from 10 years of age.

Initiating Therapy at Diagnosis

C: A home-based programme for initial management and education of children with diabetes and their families is an appropriate alternative to a hospital-based programme.

Continuing Management

Insulin Regimen

B: Intensive insulin therapy should be delivered as part of a comprehensive support package.

C: The insulin regimen should be tailored to the individual child to achieve the best possible glycemic control without disabling hypoglycemia.

Dietary Management

B: Dietary advice as part of a comprehensive management plan is recommended to improve glycemic control.

Psychological Interventions

B: Regular assessment for psychological problems, especially maladaptive coping strategies and eating disorders is recommended.

A: The use of cognitive coping strategies targeted at diabetes-specific problems is recommended.

B: Parental support and family communication should be encouraged, with targeted psychological treatment of family disruption and related stress factors.

Long Term Complications and Screening

Risk of Microvascular Complications

A: To reduce the risk of long term microvascular complications, the target for all young people with diabetes is the optimising of glycemic control towards a normal level.

Screening for Early Signs of Microvascular Disease

C: Young people with diabetes should receive examination of the retina annually from the age of 12 years.

C: Young people with diabetes should have their urine microalbuminuria (overnight albumin excretion rate [AER] or first morning albumin/creatinine ratio [ACR]) tested annually from the age of 12 years.

D: Blood pressure should be measured annually in young people with diabetes from the age of 12 years.

Associated Conditions

C: Young people with diabetes should be screened for thyroid and coeliac disease at onset of diabetes and at intervals throughout their lives.

Lifestyle Management

Delivery of Lifestyle Intervention

Which Lifestyle Interventions Have Been Shown to Work in Diabetes?

A: Patients with diabetes should be offered lifestyle interventions based on a valid theoretical framework.

B: Education programmes, computer-assisted packages and telephone prompting should be considered as part of a multidisciplinary lifestyle-intervention programme.

Training Health Professionals to Teach Lifestyle Interventions

B: Health care professionals should receive training in patient-centred interventions in diabetes.

Quality of Life and Depression

Depression and Diabetes

B: Health care professionals should be aware of the effects of depression on diabetes.

B: All people with diabetes should be screened for depression and offered appropriate therapy.

B: Selective serotonin reuptake inhibitors (SSRIs) are recommended in preference to tricyclic antidepressants for treatment of depression in patients with diabetes.

Diabetes Control and Quality of Life

B: Patients and health care professionals should make every effort to avoid severe hypoglycemia, particularly in those who are newly diagnosed.

Smoking Cessation

Assessment of Readiness to Change Smoking Behavior

D: A model using stages of change may help health care professionals understand how ready an individual is to quit smoking.

First Line Treatments

A: Health care professionals involved in caring for patients with diabetes should advise them not to smoke.

B: Nicotine replacement therapy should be provided for smokers of more than 15 cigarettes per day who are trying to quit. Therapy in a form acceptable to the patient should be offered for up to eight weeks.

B: Bupropion therapy (in the absence of contraindications) could be used alone or with nicotine replacement, if blood pressure is monitored.

Other Treatments

B: Other therapies which may be considered include clonidine and nortriptyline, however care should be taken to monitor for adverse effects.

B: Acupuncture or silver acetate should not be used as part of a smoking cessation strategy.

Monitoring

B: Health care professionals should continue to monitor smoking status in all patient groups.

Exercise and Physical Activity

Effects of Physical Activity on the Prevention of Diabetes

B: All people should be advised to maintain at least moderate levels of physical activity (e.g., daily walking) as a lifelong lifestyle modification.

Physical Activity and Exercise for People With Diabetes

D: Exercise and physical activity (involving aerobic and/or resistance training) should be performed on a regular basis.

D: Advice about exercise and physical activity should be individually tailored and diabetes-specific and should include implications for glucose management.

C: To maximise adherence, exercise programmes should be home-based and should be accompanied by ongoing support which includes education in cognitive behaviour skills and advice tailored to the individual´s stage of change.

Advice for Patients Taking Insulin or Oral Antidiabetic Drugs

C: Individualised advice on avoiding hypoglycemia when exercising by adjustment of carbohydrate intake, reduction of insulin dose, and choice of injection site, should be given to patients taking insulin.

Diabetic Complications and Exercise

D: Patients with existing complications of diabetes should seek medical review before embarking on exercise programmes.

D: A gradual introduction and initial low intensity of physical activity should be recommended for sedentary people with diabetes.

Healthy Eating

Dietary Intervention to Prevent the Onset of Diabetes

B: Overweight individuals and those at high risk of developing diabetes should be encouraged to reduce their risk by lifestyle changes.

Assessing Readiness to Change Dietary Behavior

D: Before giving dietary advice to patients with diabetes, assessment of readiness to change diet behaviour should be undertaken.

Encouraging Dietary Change in Clinical Practice

B: Clinical interventions aimed at dietary change are more likely to be successful if a psychological approach based on a theoretical model is included.

Alcohol

B: Patients with diabetes should be advised that they may drink up to 3 units of alcohol with a minimal effect on blood glucose. Patients should be advised that if exercise and consumption of alcohol are combined there may be a greater lowering of blood glucose.

Management of Diabetic Cardiovascular Disease

Primary Prevention of Coronary Heart Disease

Pharmacological Therapy

Glucose Lowering

A: Metformin should be considered as the first-line oral hypoglycemic agent in overweight patients with diabetes.

Antihypertensive Therapy

A: Hypertension in people with diabetes should be treated aggressively with lifestyle modification and drug therapy.

A: Target diastolic blood pressure in people with diabetes is ≤80 mm Hg.

D: Target systolic blood pressure in people with diabetes is <140 mm Hg.

Aspirin Therapy

B: Aspirin (75 mg) should be considered for all patients who have diabetes and well-controlled hypertension whose risk of a coronary event is estimated to be >20% over 10 years.

Lipid Lowering

D: As for non-diabetics, lipid lowering drug therapy should be considered for primary prevention in patients with type 2 diabetes without evidence of nephropathy when the 10 year risk of a major coronary event is ≥30% using the Joint British Chart.

D: Current assessment methods may underestimate risk in patients with type 1 diabetes and in patients with type 2 diabetes and nephropathy. Lipid lowering drug therapy should be considered at a lower risk threshold in these individuals.

Management of the Patient with Diabetes and New or Established Vascular Disease

Use of Insulin

B: Patients with diabetes should be considered for intensive insulin treatment following acute myocardial infarction.

Thrombolysis

A: Patients with diabetes should be given thrombolytic therapy following myocardial infarction.

Primary Coronary Angioplasty for Acute Myocardial Infarction

C: Patients with diabetes should be considered for primary angioplasty for acute myocardial infarction.

Beta-blockers

A: Beta-blocker therapy should be considered for all patients following myocardial infarction.

Antiplatelet Therapy

A: Aspirin (75 mg per day) should be given routinely and continued long term in patients with diabetes and coronary heart disease.

B: Addition of clopidogrel 75 mg daily to usual aspirin therapy should be considered for patients with diabetes and a past history of coronary heart disease presenting with acute coronary syndromes.

Angiotensin-converting Enzyme (ACE) Inhibitors

Angiotensin-converting enzyme inhibitor therapy should be given to patients with diabetes who fall into any of the following categories:

B: following myocardial infarction with or without left ventricular dysfunction

B: heart failure due to left ventricular systolic dysfunction

A: aged >55 years and who smoke, have total cholesterol >5.2 mmol/l, high-density lipoprotein cholesterol $\leq$0.9 mmol/l, microalbuminuria or hypertension.

A: In post myocardial infarction patients with left ventricular dysfunction, angiotensin-converting enzyme inhibitor therapy should be considered within 48 hours of the onset of symptoms.

Lipid Lowering

B: If total cholesterol is >5.0 mmol/l, statin therapy to reduce cholesterol should be initiated and titrated as necessary to reduce total cholesterol to <5.0 mmol/l.

B: In patients with established cardiovascular disease who are not receiving statin therapy and whose total cholesterol is <5.0 mmol/l and high-density-lipoprotein cholesterol <1.0 mmol/l, gemfibrozil should be considered.

Coronary Revascularisation

B: For patients with diabetes and multivessel disease, coronary artery bypass grafting (CABG) with use of the internal mammary arteries is preferred over percutaneous transluminal coronary angioplasty (PTCA).

A: Patients with diabetes undergoing angioplasty should be treated with stents where feasible, and receive adjunctive therapy with a platelet glycoprotein IIb/IIIa receptor antagonist.

Management of Diabetic Nephropathy

Screening

D: All patients with diabetes should have their urinary albumin concentration and serum creatinine measured at diagnosis and at regular intervals, usually annually.

D: Urinary albumin concentration should be measured using a first morning urine sample and the urinary albumin:creatinine ratio should be measured by a laboratory method or a near-patient test specific for albumin at low concentration.

D: An abnormal result should be confirmed by a further sample without delay.

Prevention of Diabetic Nephropathy

A: Good glycemic control (haemoglobin A_1c [HbA_1c] around 7%) should be maintained in all patients with diabetes to reduce the risk of developing diabetic nephropathy.

A: Tight blood pressure control (<140/80 mm Hg) in patients with type 2 diabetes should be maintained to reduce the risk of developing diabetic nephropathy.

Treatment of Diabetic Nephropathy

Blood Pressure Control

A: Blood pressure should be maintained <140/80 mm Hg in all patients with diabetes.

Angiotensin-converting Enzyme Inhibitor Therapy

A: Patients with microalbuminuria or proteinuria should be commenced on an angiotensin-converting enzyme inhibitor.

Angiotensin II Antagonists

A: Patients with microalbuminuria or proteinuria should be considered for angiotensin II antagonist therapy.

Dietary Protein

A: Patients with type 1 diabetes, proteinuria and a reduced glomerular filtration rate [GFR] should reduce dietary protein intake to 0.6-0.8 g/kg/day.

Prevention of Visual Impairment

Risk Identification and Prevention

Risk Factors for Diabetic Retinal Disease

B: Patients with multiple risk factors should be considered at high risk of developing diabetic retinal disease.

Risk Factor Modification

A: Good glycemic control (haemoglobin A_1c ideally around 7%) and blood pressure control (<140/80 mm Hg) should be maintained to prevent onset and progression of diabetic eye disease.

B: Sight-threatening retinal disease, if present, should be stabilised before rapid clinical improvements in glycemic control are achieved.

Screening

B: Systematic annual screening for diabetic retinal disease should be provided for all people with diabetes.

A: Patients with type 2 diabetes should be screened from diagnosis.

C: Patients with type 1 diabetes should be screened from age 12 years. If onset of type 1 diabetes is post-puberty, screening should start three years after diagnosis.

How Should Screening Be Performed?

C: Retinal photography or slit lamp biomicroscopy used by trained individuals should be used in a programme of systematic screening for diabetic retinopathy.

C: Dilated direct ophthalmoscopy should only be used for opportunistic screening.

D: Screening modalities should aim to detect sight threatening retinal disease with a sensitivity $\geq$ 80% and specificity $\geq$ 95%.

B: Patients with ungradeable retinal photographs should receive slit lamp and indirect ophthalmoscopy examination where possible.

D: Where possible and practical, screening should be performed at a site convenient to patients.

Grading and Quality Assurance

C: Retinal photographs should be graded using digital images or 35 mm film by an appropriately trained grader.

D: At least 1% of all screening events (photography or slit lamp) should be reviewed.

Treatment

Laser Photocoagulation

A: All patients with sight-threatening retinopathy (moderate proliferative diabetic retinopathy or worse) should receive laser photocoagulation.

A: Patients with severe pre-proliferative or mild proliferative diabetic retinopathy should receive close follow up or laser photocoagulation.

A: Focal or modified grid laser photocoagulation should be used for patients with focal clinically significant macular oedema but not for patients with ischaemic maculopathy.

A: Diffuse maculopathy should be treated if there is a concern that the disease is progressing.

Vitrectomy

B: Patients with type 1 diabetes and persistent vitreous haemorrhage should be referred for early vitrectomy.

B: Vitrectomy should be performed for tractional retinal detachment threatening the macula and should be considered for severe fibrovascular proliferation.

D: Vitrectomy should be considered in patients with diffuse diabetic macular oedema.

Cataract Extraction in Patients with Diabetes

B: Cataract extraction should not be delayed in patients with diabetes.

C: Cataract extraction is advised when sight-threatening retinopathy cannot be excluded.

C: When cataract extraction is planned in the context of advanced disease which is not stabilised prior to surgery, the risk of progression and the need for close postoperative review should be fully discussed with the patient.

Method of Assessing Retinopathy

Either good quality 7-field stereo photography or slit lamp biomicroscopy (both dilated) carried out by an appropriately experienced ophthalmologist should be used to investigate:

A: Clinically significant macular oedema (CSMO)

B: Proliferative diabetic retinopathy and severe non-proliferative diabetic retinopathy.

Rehabilitation

D: Community support, low vision aids and training in their use should be provided to people with diabetes and visual impairment.

Management of Diabetic Foot Disease

Care Management

Patient Education

B: Foot care education is recommended as part of a multidisciplinary approach in all patients with diabetes.

Structured Foot Review

D: All patients with diabetes should be screened for foot disease.

C: Clinical neuropathy disability scores, 10 g monofilaments, or vibration perception thresholds are all appropriate methods for neuropathy screening.

Structured Foot Care

C: All patients with diabetes should have access to structured diabetic foot care.

Footwear, Orthoses and Total Contact Casting

B: Patients with diabetic foot disease should be advised to wear high-quality, cushioned-soled trainers rather than ordinary shoes.

B: Custom-built footwear or orthotic insoles should be used to reduce callus severity and ulcer recurrence.

B: Patients who have unilateral plantar ulcers should be considered for treatment using total contact casting to optimise the healing rate of ulcers.

Arterial Reconstruction

B: All patients with tissue loss and arterial disease should be considered for arterial reconstruction.

Treatment

Pharmacological Therapy

A: In non-healing chronic neuropathic ulcers after optimal pressure relief, use of topical arginine glycine aspartic acid (RGD) peptide, CT-102 or becaplermin should be considered to speed up healing rates.

B: Subcutaneous granulocyte colony-stimulating factor (g-csf) should be considered in the treatment of diabetic foot infections.

Tissue Replacement Therapy and Maggots

B: Treatment of diabetic ulcers using living human tissue replacement should be considered in refractory ulcers provided the patient meets strict exclusion criteria on infection, circulation and ulcer size and depth.

Painful Diabetic Neuropathy

A: Tricyclic antidepressants should be used as first line therapy in painful diabetic neuropathy.

B: Gabapentin is also recommended in painful diabetic neuropathy and is associated with fewer side effects than tricyclic antidepressants and older anticonvulsants.

A: Topical capsaicin should be considered for the relief of localised neuropathic pain.

Charcot´s Foot

C: Diagnosis of Charcot´s foot should be made by clinical examination supported, where available, by the use of thermography.

D: Total contact casting and non-weight bearing are effective treatments for acute Charcot´s foot.

Management of Diabetes in Pregnancy

Pre-pregnancy Care

C: Pre-pregnancy care provided by a multidisciplinary team is strongly recommended for women with diabetes.

Nutritional Management

D: Dietetic advice should be available in all diabetic antenatal clinics, and should encourage diets with high levels of complex carbohydrates, soluble fibre and vitamins, and reduced levels of saturated fats.

B: All women with diabetes should be prescribed pre-pregnancy folate supplementation (c. 4 mg), continuing up to 12 weeks gestation.

Optimisation of Glycemic Control

D: Before and during pregnancy, women with diabetes should aim to have blood glucose between 4 and 7 mmol/l.

Complications During Pregnancy

Microvascular Complications

Retinopathy

C: Fundal examination prior to conception and during each trimester is advised. More frequent assessment may be required in those with poor glycemic control or hypertension.

C: Early referral of pregnant women with moderate retinopathy to an ophthalmologist is recommended due to the potential for rapid development of neovascularisation.

C: Women should be reassured that tight glycemic control during and immediately after pregnancy can effectively reduce the long term risk of retinopathy in future.

Infants of Mothers with Diabetes

B: Breast feeding is recommended for infants of mothers with diabetes, but mothers should be supported in the feeding method of their choice.

Gestational Diabetes

Management of Gestational Diabetes Mellitus

B: Women with gestational diabetes should receive intensive management with diet and/or insulin if macrosomia is suspected or if blood glucose levels are in the range for established diabetes.

Definitions:

Grades of Recommendation

A: At least one meta-analysis, systematic review, or randomized controlled trial rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomized controlled trials, or randomized controlled trials with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or randomized controlled trials with a low risk of bias

Meta-analyses, systematic reviews, or randomized controlled trials with a high risk of bias

2++: High quality systematic reviews of case control or cohort or studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g. case reports, case series

4: Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The specific type of supporting evidence is explicitly identified in each section of the guideline.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of diabetes can help reduce the burden of long-term complications, both microvascular and macrovascular, as well as improve pregnancy outcomes for the mother with diabetes.

POTENTIAL HARMS

Insulin therapy

- The risk of hypoglycemia increases with intensive therapy, but rapid acting insulin analogues, as part of a three or four injection regimen can reduce hypoglycemia.
- Severe hypoglycemia may adversely affect quality of life in patients treated with insulin, particularly in those newly diagnosed.

Pharmacotherapy for smoking cessation

- Combination of bupropion with nicotine patch increases blood pressure in some patients.
- There is a risk of seizure with bupropion therapy; a lower dose of bupropion is recommended for patients on oral hypoglycemic agents or insulin.
- There are potential side effects with clonidine use.

Exercise and physical activity

- Exercise with normal insulin dose and no additional carbohydrate significantly increases the risk of hypoglycemia during and after exercise. Patients using oral antidiabetic drugs, such as sulphonylureas, may also be at risk of hypoglycemia.
- There is a higher risk of myocardial infarction after heavy exertion in sedentary compared with non-sedentary people with type 1 diabetes.

Aspirin and clopidogrel therapy

- There is a risk of bleeding with aspirin therapy. The risk is increased with the combination of aspirin and clopidogrel.

Angiotensin-converting enzyme (ACE) inhibitor therapy

- Angiotensin-converting enzyme inhibitors can induce cough or rash.

Subgroups Most Likely to be Harmed:

Patients with newly diagnosed diabetes are at greater risk for severe hypoglycemia during the start of insulin therapy.

CONTRAINDICATIONS

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Angiotensin-converting enzyme (ACE) inhibitors are contraindicated in the presence of significant bilateral renal artery stenosis because of the risk of acute renal failure.

QUALIFYING STATEMENTS

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This guideline is not intended to be construed or to serve as a standard of clinical care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at

the same results. The ultimate judgment regarding a particular clinical procedure or treatment plan must be made in light of the clinical data presented by the patient and the diagnostic and treatment options available. However, it is advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient´s case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Scottish Diabetes Framework seeks to draw together existing guidance and best practice. It should be read in conjunction with the "Management of diabetes" guideline produced by the Scottish Intercollegiate Guidelines Network (SIGN) and the clinical standards for diabetes developed by the Clinical Standards Board for Scotland (www.clinicalstandards.org) which were both published in November 2001. The standards and the clinical guideline should be viewed as integral parts of the Framework.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of diabetes. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2001 Nov. 50 p. (SIGN publication; no. 55). [388 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Nov

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The guideline was developed by seven multidisciplinary development groups coordinated by a steering group comprising the leaders of each of the groups, chaired by Professor Ian Campbell, Consultant Physician, Victoria Hospital, Kirkcaldy.

SOURCE(S) OF FUNDING

Scottish Executive Health Department

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Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

This is a review of the Scottish Intercollegiate Guidelines Network (SIGN) guidelines on diabetes published in 1996-1997 that addressed: visual impairment (SIGN 4), pregnancy (SIGN 9), children and young people (SIGN 10), renal disease (SIGN 11), foot disease (SIGN 12), and cardiovascular disease (SIGN 19).

This guideline was issued in 2001 and will be reviewed in 2004 or sooner if new evidence becomes available.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- HTML format
- Portable Document Format (PDF)

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Quick reference guide: Management of diabetes, Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site
- Guideline 55: management of diabetes. Supporting material [online]. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site
- Scottish diabetes framework. Scottish Executive Health Department, 2001 Nov. 108 p. Available at http://www.scotland.gov.uk/library5/health/sdf-00.asp

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 17, 2002. The information was verified by the guideline developer on July 11, 2002.

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